



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,613	02/29/2000	DEBORAH C. MASH	N08-002	8931

7590 11/26/2001
COLEMAN SUDOL
708 THIRD AVENUE
14TH FLOOR
NEW YORK, NY 10017

EXAMINER

STILLER, KARL J

ART UNIT	PAPER NUMBER
----------	--------------

1617

DATE MAILED: 11/26/2001

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/486,613

Applicant(s)

MASH, DEBORAH C.

Examiner

Karl Stiller

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, Claim(s) 1-5, drawn to a method of alleviating pain in a patient, comprising the administration of noribogaine.

Group II, Claim(s) 6-9, drawn to a method of alleviating pain in a patient, comprising the concomitant administration of noribogaine and one or more opioid antagonists.

Group III, Claim(s) 10-18, drawn to a method of treating drug dependence or abuse in a patient, comprising the administration of noribogaine.

Group IV, claim(s) 19-24, drawn to a pharmaceutical composition, comprising noribogaine and one or more opioid antagonists.

Claims 1-5, drawn to a method of alleviating pain in a patient, comprising the administration of noribogaine, is considered the main invention since it is the first invention recited in the Claims and there is no additional category of invention relating thereto (See 37 CFR 1.475 (d)).

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups I-IV lack a common inventive concept common to Claims of all Groups. The Claims of Group I are

Art Unit: 1617

drawn to a method of alleviating pain in a patient comprising the administration of noribogaine. The Claims of Group II are drawn to a method of alleviating pain comprising the concomitant administration of noribogaine and an opioid antagonist. The Claims of Group III are drawn to a method of treating drug dependence or abuse. The Claims of Group IV are drawn to a pharmaceutical composition comprising noribogaine and one or more opioid antagonists. The special technical feature uniting the Claims of Group I is the alleviation of pain comprising the administration of noribogaine. The Claims of Groups II-IV are not seen to have this special technical feature because the Claims of Group II require the concomitant administration of noribogaine and an opioid antagonist; the Claims of Group III are not drawn to the alleviation of pain, but rather the treatment of drug dependence or abuse employing noribogaine; the Claims of Group IV are drawn to a pharmaceutical composition comprising noribogaine and one or more opioid antagonists.

The above delineated inventions differ as methods and a composition and are independent and patentably distinct each from the other. The grouped inventions patentably distinct, a reference which would anticipate, or make obvious, the inventions of Group I, Group II, Group III, or Group IV would not necessarily obviate or anticipate the inventions in the other Groups. The searches are not co-inclusive as indicated by the diverse nature of the subject matter, thus would represent an undue burden on Examiner. One skilled in the art would readily practice the invention of one of the above Groups without infringing and/or practicing the invention of another Group. The subject matter is unique and has acquired a separate status in the art and is fully capable of

Art Unit: 1617

supporting separate patents. For the foregoing reasons restriction is proper for examination purposes. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

A telephone call was made to Henry D. Coleman on November 19, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Should applicants traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variations or clearly admit on the record that this is the case. In either instance, if Examiner finds one of the inventions unpatentable over the prior art, the evidence may be used in a rejection under 35 USC 103 of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl Stiller whose telephone number is 703-306-3219. The examiner can normally be reached Monday through Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached at 703-308-4612. The fax phone number for

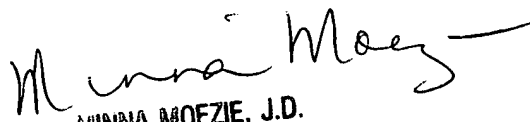
Application/Control Number: 09/486,613
Art Unit: 1617

Page 5

the organization where this application or proceeding is assigned is 703-308-4556 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Stiller: ks
November 19, 2001


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800